ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115

Majority (202) 225–2927 Minority (202) 225–3641

August 7, 2015

Ms. Cate Dyer Founder and CEO StemExpress 778 Pacific Street Placerville, CA 94501

Dear Ms. Dyer:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce seeks information and requests a briefing regarding your organization's practices relating to human fetal tissue collection, sale and/or donation.

Several videos made public in recent weeks have raised questions regarding the buying, selling, and research use of human fetal tissue. A recent *New York Times* article reported that StemExpress is a major supplier of fetal tissue, and that StemExpress's revenue was reported in August 2014 to be \$2.2 million, with fetal tissue accounting for about 10 percent of the company's business. The article also reported that StemExpress employs 37 people, including procurement technicians to obtain fetal tissue. Further, it said that a vial containing five million frozen fetal liver CD 133+ stem cells can cost more than \$24,000 and shipping fees abroad can cost thousands of dollars. This information suggests there may be a basis to explain StemExpress's pricing, and how costs are determined.

We also note that a StemExpress brochure contains an endorsement from a chapter of Planned Parenthood, and a flyer from StemExpress aimed at clinics providing fetal tissue states that the clinics would be "contributing to the fiscal growth of" their clinics. These statements raise questions about the nature of the relationship between StemExpress and providers of fetal tissue, and whether the fetal tissue is provided with a strictly donative intent.

Under the NIH Revitalization Act of 1993, it is "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce." While this provision prohibits the sale or purchase of fetal tissue itself, the term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of

human fetal tissue. As the committee with legislative jurisdiction over the NIH Revitalization Act of 1993, we have an oversight responsibility and interest in determining whether there is adequate compliance with the law, and/or whether the law is adequately meeting ethical and moral concerns.

To assist the committee's examination, we respectfully request that StemExpress provide a briefing to committee staff no later than August 21, 2015. StemExpress should be prepared to address the following issues:

- 1. Your organization's procedures to assure proper informed consent for fetal tissue donation.
- 2. Your organization's practices for collecting fetal tissue, including guidance to, and training for, agents or representatives involved in the acquisition of fetal tissue.
- 3. Your organization's practices and/or policies relating to the quality or quality control of fetal tissue, and how your organization decides what types of fetal tissue to collect.
- 4. The prices or fees that StemExpress pays for each type of fetal tissue, and how much StemExpress paid in 2014 for fetal tissue.
- 5. The prices or fees that StemExpress sets for each type of fetal tissue provided to researchers, including what guidance or criteria, if any, StemExpress provides to researchers on prices and fees, and the total amount of fees collected and costs expended by StemExpress relating to fetal tissue.
- 6. The number of years StemExpress has engaged in fetal tissue collection and whether and how StemExpress assures that the collection, sale and/or donation of fetal tissue is in compliance with federal and state legal requirements, or is in accordance with rules made by ethics boards by institutions buying fetal tissue from StemExpress.

In addition to this briefing, we respectfully request that StemExpress preserve and retain all documents relating or referring to the collection, sale and/or donation of fetal tissue.

If you have any questions about this letter, please contact Charles Ingebretson of the committee staff at (202) 225-2927.

Sincerely,

Fred Upton Chairman

tool Mp

Tim Murphy

Chairman

Subcommittee on Oversight and Investigations

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Joe Barton
Chairman Emeritus

Marsha Blackburn Vice Chairman

Harrhe Bleckburn

Joe Pitts
Chairman

Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member

The Honorable Diana DeGette, Ranking Member Subcommittee on Oversight and Investigations

The Honorable Gene Green, Ranking Member Subcommittee on Health